Attorney Docket No. 100717-691 KGB
Confirmation No. 4318

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT	:	Stefan WILLMANN et al
SERIAL NO.	:	10/598,416
CUSTOMER NO.	:	27384
FILED	:	August 29, 2006
FOR	:	IMPROVED METHOD FOR THE TIME DOSAGE OF MEDICAMENTS
ART UNIT	:	To Be Assigned
EXAMINER	:	To Be Assigned

February 23, 2007

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

SIR:

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicants respectfully request that the Examiner consider the references listed on the attached Form PTO/SB/08.

I. Timeliness, Fees and Certifications in lieu of Fees

This information disclosure statement is being filed within three months of the filing date of the application, or within three months of entry into the national stage, or before the mailing of a first Office Action on the merits. Pursuant to 37 CFR § 1.97(b), consideration of this information disclosure statement does not require a fee or a statement under 37 CFR § 1.97(e). However, should the Assistant Commissioner determine that a fee is, in fact, due, the Assistant Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263.

II. Copies of Listed References

Copies of all references listed on the attached Form PTO/SB/08 are being supplied. Copies of U.S. patents are not included pursuant to Pre-OG Notice dated July 11, 2003.

III. Concise Statement of Relevance

All references listed on the attached Form PTO/SB/08 are referred to in the specification which indicates the degree of relevance.

The Examiner will note that English language counterparts or Abstracts of non-English language references are also enclosed, as follows:

DE 101 60 270 – Cited on pages 1 and 5 of the specification. Corresponds to US2005119832. Abstract provided.

DE 103 45 836 – Cited on pages 1 and 5 of the specification. Corresponds to US2005075274. Abstract provided.

DE 103 45 837 – Cited on page 1 of the specification. Corresponds to US2005074803. Abstract provided.

Consideration of the foregoing in relation to this application is respectfully requested.

Respectfully submitted,

NORRIS McLAUGHLIN & MARCUS, P.A.

By /Kurt G. Briscoe/

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PTO/SB/08a (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	10598416
Filing Date	2006-08-29
First Named Inventor	Stefan WILLMANN et al
Art Unit	
Examiner Name	
Attorney Docket Number	100717-691 KGB

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	1	101 60 270	DE		2003-06-26	BAYER AG		☐
	2	103 45 836	DE		2005-04-21	BAYER TECHNOLOGY SERVICES		☐
	3	103 45 837	DE		2005-04-21	BAYER TECHNOLOGY SERVICES		☐

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NON-PATENT LITERATURE DOCUMENTS [Remove]

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Product Information - "Diprifusor™- Target Controlled Infusion (TCI) in anaestehetic practice"; AstraZeneca Anaesthesia, New Edition (1999), Alderley House, Alderley Park, UK	☒
	2	WILLMANN, Stefan et al; "PK-Sim®: a physiologically based pharmacokinetic 'whole-body' model"; Biosilico Vol. I, No 4, (September 2003) pages 121-124, Elsevier Science Ltd.	☒
	3	PRICE, Paul S.; "Modeling interindividual variation in physiological factors used in PBPK models of humans"; Critical Reviews in Toxicology, 33(5); pages 469-503 (2003) Taylor and Francis, Inc.	☒
	4	OHNISHI, A.; "A review of clinical use of theophylline in acute asthema: factors influencing kinetic disposition and drug interactions"; Methods Find Exp. Clin Pharmacol 22(4); pages 253-258, (2000) Prous Science	☒
	5	MITENKO, Paul A, et al; "Pharmacokinetics of intravenous theophylline"; Clinical Pharmacology Therapeutics; 14, (1973) pages 509-513, Montreal, Quebec, Canada	☒
	6	JAMESON, John P., et al; "Theophylline Pharmacokinetics in black Zimbabewean males"; Therapeutic Drug Monitoring, 12, pages 54-58 (1990) Ravene Press, Ltd. New York	☒
	7	GAL, Peter et al; "Theophylline disposition in obesity"; Clin. Pharmacol. Ther (April 1978), Vol. 23, No. 4; The C.V. Mosby Co., pages 438-444	☒
	8	JACKSON, S.H.D.; et al; "The relationship between theophylline clearance and age in adult life": Eur. J. Clin Pharmacol, Springer-Verlag (1989) 36: pages 29-34	☒
	9	KATA, Z et al; "Developmental changes of unbound theophylline"; Department of Pediatrics, Gifu University School of Medicine, 40 Tsukasa, Gifu 500 Japan	☒

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	10	VALENTI, S.; "Bioavailability and pharmacokinetics of a new controlled-release theophylline preparation in the form of capsules containing Pellets"; Respiration 52; (1987) pages 195-200	☒
	11	MULLER et al; "Theophylline kinetics in peripheral tissues in vivo in humans"; Naunyn-Schmiedeberg's Arch Pharmaol (1995) 352; pages 438-441	☒
	12	MEYER, Marvin c.; "Bioequivalence of immediate-release theophylline capsules"; Biopharmaceuticcs & Drug Disposition (1999) 20; pages 417-419	☒

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Kurt G. Briscoe/	Date (YYYY-MM-DD)	2006-02-23
Name/Print	KURT G. BRISCOE	Registration Number	33141

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.